

### REMARKS

This amendment and response is in reply to the office action that was mailed on May 12, 2009. In that office action, claims one, 3-4, 6-9, and 12-24 were rejected.

With this response, claims 1, 3-4, 7, 9, and 23-24 have been amended. Claims 1, 3-4, 6-9, and 12-24 remain pending in the application.

#### **Rejections under 35 U.S.C. § § 102 and 103**

Claims 1, 6, 9, 13, and 23-24 were rejected under 35 U.S.C. § 102 as anticipated by Kuczynski, US patent number 5,722,965 ("Kuczynski").

Kuczynski provides a low-profile ostomy system that is directed to providing wrinkle free removal and repositioning of an ostomy pouch around a stoma (column 1, lines 5-12). Kuczynski at column 1, lines 21-31 discloses that removal of an adhesively secured pouch from a body side wafer can cause the base plate or the body side wafer to wrinkle. Kuczynski discloses that wrinkles in the body side wafer or in the base plate are detrimental to the integrity of the seal between the pouch and the wafer.

In contrast, the pending application is directed to solving a different problem as disclosed in the application as filed at page 5, lines 19-29 and at page 6, lines 9-12 where it is taught that embodiments of the instant application provide a solution to avoid tearing the ostomy collecting bag during removal of the bag from a body side wafer.

It is believed that the differences between the instant application and Kuczynski as described herein result in the instant application providing patentable subject matter over Kuczynski.

In particular, the Examiner interprets Kuczynski to disclose an ostomy device as shown in Figure 1 and Figures 9-10 that includes a body side member 14 and a collecting bag 12. The Examiner takes the position that the body side member 14 includes a first flange 76 (as shown in Figure 9) and that the collecting bag 12 includes a coupling element 50 having a second flange 60 (as shown in Figure 9). The Examiner interprets Kuczynski to provide a flexible layer 84 that is bonded to the first flange 76, such that the flexible layer 84 is thus provided on the body side member 14. Kuczynski does not provide a flexible layer that is bonded to the second flange 60

(i.e., the collecting bag 12). In fact, in reference to Figures 9-10 Kuczynski discloses at column 4, lines 54-67 that base plate 50 is formed from a foam tape 60 having an adhesive surface 62.

In contrast, the claimed embodiments are directed to a reinforced second flange on the collecting bag, and Kuczynski does not teach or suggest the claimed reinforced second flange, as detailed below.

With this response, independent claim 1 has been amended to require a collecting bag including a coupling element having a second flange . . . and a flexible layer bonded to an outer surface of said second flange and an adhesive layer affixed to said flexible layer so that said flexible layer is sandwiched between the adhesive layer and the second flange, said bond between the outer surface of the second flange and the flexible layer being stronger than a connection between the first flange and the adhesive layer of said collecting bag coupling element, said flexible layer having a yield strength exceeding an adhesive strength of the adhesive layer. Kuczynski does not teach or suggest at least the limitation of adhesive layer affixed to the flexible layer so that the flexible layer is sandwiched between the adhesive layer and a second flange.

It is believed that amended independent claim 1 recites patentable subject matter over Kuczynski. Claims 6, 9, and 23-24 further define patently distinct amended independent claim 1.

With this response, independent claim 9 has been amended to more particularly point out and distinctly claim that the ostomy collecting bag comprises an adhesive layer affixed to said flexible layer so that said flexible layer is sandwiched between the adhesive layer and the coupling element flange. Kuczynski does not teach or suggest at least this limitation.

It is believed that amended independent claim 9 recites patentable subject matter over Kuczynski. Claim 13 further defines patently distinct amended independent claim 9.

Thus, it is respectfully requested that the rejections to claims 1, 6, 9, 13, and 23-24 under 35 U.S.C. § 102 as anticipated by Kuczynski be withdrawn.

Claims 3-4, 7-8, 12, and 14-22 were rejected under 35 U.S.C. § 103 as unpatentable over Kuczynski.

The Examiner takes the position that Kuczynski discloses the need for the second flange to be deformable during removal of the ostomy bag and concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the second

flange of Kuczynski with a lower tensile strength. We disagree, but also note that a *prima facie* case of obviousness cannot be established over Kuczynski since the reference fails to teach or suggest all limitations of the pending claims.

In particular, Kuczynski explicitly discloses that the base plate 50 is formed of a foam tape 60 and that the composite 76 is formed of the same foam tape as a foam tape 60. Moreover, the Examiner concedes at page 3 of the office action that "The first flange 76 and the second flange 60 comprise the identical foam material, as disclosed in column 4, lines 33-36, and column 5, lines 35-38, and therefore have the same tensile strength." One of ordinary skill in the art would not be motivated to modify the disclosure in Kuczynski (directed to providing wrinkle free attachment of the ostomy bag to the base plate) by providing the second flange with different properties than the first flange, as this modification would be likely to render Kuczynski unsatisfactory for the intended purpose of providing wrinkle free attachment. For at least this reason, a *prima facie* case of obviousness cannot be established in rejecting the pending claims over Kuczynski.

In any regard, the flexible layer 84 provided by Kuczynski is attached to the body side member 14 (as acknowledged by the Examiner at page 3 of the office action) and not the ostomy collecting bag as required by the pending claims. In diametric contrast, pending independent claim 14 requires a flexible layer bonded to an outer surface of the second flange that is provided by the ostomy collecting bag, which is not taught or suggested by Kuczynski.

It is believed that for all of the above reasons independent claims 1, 9, and 14 provide patentable subject matter that is not anticipated or rendered obvious over Kuczynski. Claims 3-4 and 7-8 further define patently distinct amended independent claim 1; claim 12 further defines patently distinct amended independent claim 9; and claims 15-22 further define patently distinct independent claim 14.

Thus, it is respectfully requested that the rejections to claims 3-4, 7-8, 12, and 14-22 under 35 U.S.C. § 103 as unpatentable over Kuczynski be withdrawn.

Applicants: Henrik Leisner  
Serial No. : 10/532,716  
Filed : 11-16-2005  
Page : 10 of 10

Attorney Docket No.: 2002027-US

### **CONCLUSION**

Applicant respectfully asserts that the pending claims 1, 3-4, 6-9, and 12-24 are in condition for allowance and notice of the same is respectfully requested.

Accompanying this reply is a separate Petition for Extension of Time Under 37 CFR 1.136(a) document. A required fee thereon will be paid via the EFS-Web system upon submission hereof.

Should issues remain outstanding, the Examiner is respectfully urged to telephone the undersigned. No additional fees are believed to be due at this time. However, the office is authorized to charge any fees actually due and credit any overpayment of fees to deposit account 50-4439.

Respectfully submitted,  
Henrik Leisner

Date: September 14, 2009

/Nick Baumann/  
Nick Baumann, Reg. No. 56,161  
Senior Patent Counsel  
Coloplast Corp., Coloplast A/S  
Customer No. 69289  
Telephone: (612) 287-4178